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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,446	08/16/2000	Fang Fang	014357/0278749	9403

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,446	FANG, FANG	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10,13-16,19,20,27-29,31-33,35 and 36* is/are pending in the application.

4a) Of the above claim(s) *13-16, 28, 32, 35, 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10,19,20,27,29,31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I (claims 7-10, 19, 20, 27, 29, 31, and 33) in the response filed February 5, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The Examiner and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Ulrike Winkler**, Group Art Unit 1648.

Information Disclosure Statement

An initialed and dated copies of Applicant's IDS form 1449, date stamped January 24, 2001, February 21, 2001, October 6, 2003 and October 20, 2003 are attached to the instant Office Action.

Claim Objections

The specification is objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos to all mentions of specific sequences in the specification and the claims. See 37 C.F.R. § 1.821(d). For example page 18, lines 18-21, of the specification, specifically refers to several peptides, yet there is no correlation in the specification that identifies these peptides with SEQ ID Nos. As a cautionary note this is <u>not</u> a complete listing of all the missing SEQ ID NOs found throughout the specification and claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-9, 19, 20, 27, 29, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair et al. (WO 91/16927, see IDS October 20, 2003) in view of King et al. (U.S. Pat. No. 6,307,026 B1) and Hodits et al. (Journal of Biological Chemistry, 1995)

The instant inventions is drawn to a multivalent recombinant antibody, comprising at least 2 (multi), four, five or more antigen binding domains. The antibody is directed to ICAM-1. The antibody is formulated for the prevention of rhinovirus infection, the formulation includes antibodies to the LDL receptor. The claims are drawn to a method of administering the antibody for the prevention of the common cold or acute otitis.

Adair et al. teaches the production of a humanized CDR- grafted antibody for the binding of ICAM-1. The antibodies have the same specificity as theR6-5-D5 antibody (page 31, lines 19-25, also see claims 1, 16). The reference teaches recombinant antibodies, having two antigen binding sites (multivalent), as an anti-inflammatory agent (see pages 32-35; page 33, lines 25-33) for the treatment of viral infection, especially rhinoviral infection (see claims 36-38), or for a method of treating inflammation (see claim 30). The Office does not have laboratory facilities to test whether the antibodies of the prior art binds ICAM-1 with a specificity of 10^8 M^{-1}. Barring any evidence to the contrary the presumption is that the prior art antibodies will bind ICAM-1 epitopes with the same specificity. The reference does not teach a multivalent recombinant antibody having more than 2 antigen binding sites.

King et al. teaches the production of multivalent antigen binding proteins =using various crosslinking reagents (see column 11, 12 and 27). Increasing the number of Fab fragments that are cross-linked increases the total binding capacity of the molecule. The reference also teaches utilizing these humanized cross-linked antibodies for therapeutic administration.

Hodits et al. teaches the production of single chain fragment antibodies against the low density lipoprotein receptor (LDL). These antibodies were able to inhibit viral infection in cells (see figure 7). The protection of the antibody was increased by binding the single chain antibodies using a *myc*-sequence tag (see page 24084, last paragraph), by making the molecule multivalent.

It would have been obvious tot one of ordinary skill in the art at the time the inventions was made to cross-link antibodies in order to increase the binding specificity of the molecule, as taught by King et al and Hodits et al. One having ordinary skill in the art would have been motivated to utilize the recombinant antibodies taught by Adair et al. and to increase there binding capacity by crosslinking the antibodies. Formulating a combination of ICAM-1 directed antibodies and LDL antibodies into a single use formulation would have been motivated by Hodits et al. which indicates that rhinoviruses gain entry into the host cell via the LDL receptor (minor group) and via the ICAM-1 (major group). A formulation containing antibodies directed to both group would provide protection against rhinovirus displaying surface molecules associated different serotypes (see Hodits et al. page 24084, column 2, 2nd paragraph). Therefore, the instant invetion directed to multivalent antibodies for the protection of rhinovirus infection is obvious Adair et al. in view of King et al. and Hodits et al.

Conclusion

No claims allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 5/17/04